Attorney Docket No. 366325-524

Inventor: Chen, et al.

What is claimed:

1. A dosage unit comprising a mucosal surface-coat-forming film, wherein the

mucosal surface-coat-forming film comprises a water-soluble hydrocolloid, an effective dose of

a sexual dysfunction active agent and a mucosal adhesion enhancer, wherein the mucosal

adhesion enhancer is a starch graft copolymer.

The dosage unit of claim 1, wherein the mucosal adhesion enhancer is a 2.

copolymer of starch and acrylic acid.

3. The dosage unit of claim 1, wherein the film exhibits a dry tack value of less than

3.5g.

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4. The dosage unit of claim 1, wherein the film exhibits a dry tack value of less than

2.0g.

5. The dosage unit of claim 1, wherein the film exhibits a wet tack value of greater

than 35g.

6. The dosage unit of claim 1, wherein the water-soluble hydrocolloid exhibits a

gelation temperature that is greater than 70°C for a 2% polymer solution.

7. The dosage unit of claim 1, wherein the water-soluble hydrocolloid exhibits a

hydration rate in 24 hours of 5-20% at 75% humidity at room temperature.

8. The dosage unit of claim 1, wherein the water-soluble hydrocolloid is a polymer

selected from the group consisting of a natural, semi-natural and synthetic biopolymer.

9. The dosage unit of claim 8, wherein the water-soluble hydrocolloid is selected

from the group consisting of a polysaccharade and a polypeptide.

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10. The dosage unit of claim 8, wherein the water-soluble hydrocolloid comprises a hydroxypropylmethylcellulose polymer.

- 11. The dosage unit of claim 10, wherein the hydroxypropylmethylcellulose polymer has a molecular weight of less than 200,000 Daltons.
- 12. The dosage unit of claim 1, wherein the film further comprises at least one of an emulsifier, a plasticizer, a taste modifying agent, a water soluble inert filler, a preservative, a coloring agent, a stabilizer and a buffering agent.
- 13. The dosage unit of claim 1, wherein the film further comprises an emulsifier present at a concentration in the range of 0.1 to 10 wt% of the dosage unit.
- 14. The dosage unit of claim 1, wherein the film further comprises a taste modifying agent comprising at least one of a sweetening agent, a flavoring agent and a taste masking agent.
- 15. The dosage unit of claim 1, wherein the film further comprises a water soluble inert filler present at a concentration in the range of 0.5 to 50 wt% of the dosage unit.
- 16. The dosage unit of claim 1, wherein the film further comprises a preservative present at a concentration in the range of 0.01 to 10 wt% of the dosage unit.
- 17. The dosage unit of claim 1, wherein the active agent is present at a concentration in the range of 0.01 to 75 wt% of the dosage unit.
- 19. The dosage unit of claim 1, wherein the sexual dysfunction active agent is sildenafil citrate.
- 20. The dosage unit of claim 1, wherein the film has a dry film thickness in the range of 1 to 20 mil.

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- The dosage unit of claim 20, wherein the film has a dry film thickness of less than 10 mils.
- 22. The dosage unit of claim 1, wherein the film exhibits a tensile strength greater than 1500 psi.
- 23. The dosage unit of claim 1, wherein the film exhibits a % elongation of less than 20%.
- 24. The dosage unit of claim 1, wherein the film exhibits a modulus in the range of 35,000 to 300,000 psi.
- 24. The dosage unit of claim 1, wherein the film exhibits a dissolution time in the range of 10 to 600 seconds upon application to an oral mucosal surface.
- 25. The dosage unit of claim 1, wherein the film exhibits a dissolution time in the range of 1 to 300 seconds upon application to an oral mucosal surface.
- 26. The dosage unit of claim 24, wherein the film exhibits a tensile strength greater than 1,500 psi, a % elongation of less than 20% and a disintegration time in the range from 1 to 300 seconds upon application to an oral mucosal surface.
- 27. The dosage unit of claim 1, wherein the active agent is encapsulated within a polymer, wherein the polymer is chemically or physically distinct from the hydrocolloid.
- 28. The dosage unit of claim 1, wherein the dosage unit comprises at least two active agents.
- 29. The dosage unit of claim 1, wherein the mucosal adhesion enhancer is present at a concentration of up to 50%.

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30. A dosage unit comprising a mucosal surface-coat-forming film, wherein the mucosal surface-coat-forming film comprises a water-soluble hydrocolloid, an effective dose of a sexual dysfunction active agent and a mucosal adhesion enhancer; wherein the active agent is encapsulated within a polymer which is chemically or physically distinct from the hydocolloid; wherein the mucosal adhesion enhancer is a starch graft copolymer; wherein the film exhibits a dry tack value of less than 3.5g, a wet tack of greater than 35g, a gelation temperature that is greater than 70°C for a 2% polymer solution, a dry film thickness of not more than 20 mil, a water content of 0.5 to 10%, a tensile strength greater than 1500 psi, a modulus in the range of 35,000 to 300,000 psi, a % elongation of less than 20%, a tear propagation resistance of 0.001 to 1 N, and a dissolution time on not more than 600 seconds upon application to an oral mucosal surface.

- 31. The dosage unit of claim 30, wherein the mucosal adhesion enhancer is a copolymer of starch and acrylic acid.
- 32. The dosage unit of claim 30, wherein the film exhibits a dry tack value of less than 2.0g.
- 33. The dosage unit of claim 30, wherein the water-soluble hydrocolloid exhibits a hydration rate in 24 hours of 5-20% at 75% humidity at room temperature.
- 34. The dosage unit of claim 30, wherein the water-soluble hydrocolloid is a polymer selected from the group consisting of a natural, semi-natural and synthetic biopolymer.
- 35. The dosage unit of claim 34, wherein the water-soluble hydrocolloid is selected from the group consisting of a polysaccharade and a polypeptide.
- 36. The dosage unit of claim 34, wherein the water-soluble hydrocolloid comprises a hydroxypropylmethylcellulose polymer.

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- 37. The dosage unit of claim 36, wherein the hydroxypropylmethylcellulose polymer has a molecular weight of less than 200,000 Daltons.
- 38. The dosage unit of claim 30, wherein the film further comprises at least one of an emulsifier, a plasticizer, a taste modifying agent, a water soluble inert filler, a preservative, a coloring agent, a stabilizer and a buffering agent.
- 39. The dosage unit of claim 30, wherein the film further comprises an emulsifier present at a concentration in the range of 0.1 to 10 wt% of the dosage unit.
- 40. The dosage unit of claim 30, wherein the film further comprises a taste modifying agent comprising at least one of a sweetening agent, a flavoring agent and a taste masking agent.
- 41. The dosage unit of claim 30, wherein the film further comprises a water soluble inert filler present at a concentration in the range of 0.5 to 50 wt% of the dosage unit.
- 42. The dosage unit of claim 30, wherein the film further comprises a preservative present at a concentration in the range of 0.01 to 10 wt% of the dosage unit.
- 43. The dosage unit of claim 30, wherein the active agent is present at a concentration in the range of 0.01 to 75 wt% of the dosage unit.
- 44. The dosage unit of claim 30, wherein the sexual dysfunction active agent is sildenafil citrate.
- 45. The dosage unit of claim 30, wherein the film has a dry film thickness in the range of 1 to 20 mil.
- 46. The dosage unit of claim 45, wherein the film has a dry film thickness of less than 10 mils.

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- 47. The dosage unit of claim 30, wherein the film exhibits a dissolution time in the range of 10 to 600 seconds upon application to an oral mucosal surface.
- 48. The dosage unit of claim 30, wherein the film further exhibits a dissintegration time in the range of 1 to 300 seconds upon application to an oral mucosal surface.
- 49. The dosage unit of claim 30, wherein the active agent is encapsulated within a polymer, wherein the polymer is chemically or physically distinct from the hydrocolloid.
- 50. The dosage unit of claim 30, wherein the dosage unit comprises at least two active agents.
- 51. The dosage unit of claim 30, wherein the mucosal adhesion enhancer is present at a concentration of up to 50%.